

## **REMARKS**

Applicant has carefully reviewed the Office Action mailed January 26, 2007 and offers the following remarks to accompany the above amendments.

Claims 1, 3, 5, 7, 9, 11-15, 17-20, 22, and 24 are pending. Claims 2, 4, 6, 8, 10, 16, 21, 23, 25 were previously cancelled. Claims 26-45 were previously withdrawn. Accordingly, claims 1, 3, 5, 7, 9, 11-15, 17-20, 22, and 24 are pending.

Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,301,499 B1 to Carlson et al. (hereinafter "Carlson"). Applicant respectfully traverses. For the Patent Office to prove anticipation, each and every element of the claims must be present in the reference. Furthermore, the elements of the reference must be arranged as claimed. MPEP § 2131.

Prior to addressing the merits of the rejection, Applicant offers the following brief summary of the present invention as claimed. The present invention provides for alignment of the heart rate variability cycle and the breathing cycle of a human subject. When aligned, the heart rate variability cycle and the breathing cycle are termed to be coherent. Maximum coherence of the heart rate variability is achieved when the breathing cycle is synchronized with the natural heart variability cycle in time and amplitude. The present invention, as claimed, monitors the natural heart rate of the human subject and provides a first biofeedback signal to the human subject to indicate that the natural heart rate has reached the maximum heart rate upon detecting a transition in the natural heart rate from a maximum heart rate. The present invention provides a second biofeedback signal to the human subject to indicate that the natural heart rate has reached the minimum heart rate upon detecting a transition in the natural heart rate from a minimum heart rate.

In contrast, the Carlson reference teaches determining an average length of RR intervals of the patient's heart beat (e.g., time between successive systolic portions of the heart beat). The average length of the RR intervals is calculated over 288 five-minute intervals during a 24 hour period and a standard deviation of the 288 average RR interval lengths is computed. (See Carlson, col. 2, ll. 1-9). The Carlson reference alternatively teaches determining an absolute value of time difference between successive RR intervals, plotting the absolute values, and calculating the area under the plot. (See Carlson, col. 2, ll. 10-18). The area under the plot is calculated only after all samples are collected. (See Carlson, Figure 7, block 38). In either

approach, the Carlson reference teaches correlating the gathered data to infer the patient's oxygen consumption. (See Carlson, col. 2, ll. 8-9 and 17-18). As such, the Carlson reference performs statistical calculations on large sets of heart beat data after the data is collected (e.g., over a 24 hour period).

Claim 1 recites, among other things, “detecting a transition in the natural heart rate from a maximum heart rate . . . .” (Emphasis added). There is no teaching or suggestion within the Carlson reference of detecting a transition in the natural heart rate from a maximum heart rate. The Carlson reference actually teaches performing a mathematical or statistical algorithm on a large series of collected data to infer oxygen consumption of the patient. Further, the Carlson reference does not perform these algorithms until the sampling is completed (e.g., after 24 hours). Accordingly, the Carlson reference does not teach or suggest detecting a transition in the natural heart rate from a maximum heart rate as claimed and does not anticipate claim 1 for at least this reason.

Additionally, claim 1 also recites “providing a first biofeedback signal to the human subject to indicate that the natural heart rate has reached the maximum heart rate . . . .” (Emphasis added). As discussed above, the Carlson reference teaches performing a mathematical or statistical algorithm on a series of collected data (e.g., over a 24 hour period) to infer oxygen consumption of the patient and does not teach or suggest detecting a transition from a maximum heart rate. As such, the Carlson reference does not provide a first biofeedback signal to the human subject to indicate that the natural heart rate has reached the maximum heart rate as claimed. Accordingly, the Carlson reference does not anticipate claim 1 for at least this additional reason.

Furthermore, claim 1 also recites “detecting a transition in the natural heart rate from a minimum heart rate . . . .” For the same reasons discussed above, the Carlson reference does not detect a transition in the natural heart rate from a minimum heart rate. Accordingly, the Carlson reference does not anticipate claim 1 for this additional reason because the Carlson reference does not teach or suggest this additional limitation of claim 1.

Likewise, claim 1 also recites “providing a second biofeedback signal to the human subject to indicate that the natural heart rate has reached the minimum heart rate.” (Emphasis added). The second biofeedback signal, which is distinctly claimed from the first biofeedback signal within claim 1, is also not taught or suggested within the Carlson reference. Additionally,

because the Carlson reference does not teach or suggest detecting a transition in the natural heart rate from a minimum heart rate, the Carlson reference does not teach or suggest providing a second biofeedback signal to the human subject to indicate that the natural heart rate has reached the minimum heart rate as claimed. Accordingly, the Carlson reference does not anticipate claim 1 for these additional reasons.

Applicant respectfully submits that multiple limitations of claim 1 are not taught or suggested within the Carlson reference. Accordingly, the rejection of claim 1 based upon the Carlson reference should be withdrawn.

Claims 1, 3, 5, 7, 9, 11-15, 17-20, 22, and 24 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,997,482 to Vaschillo et al. (hereinafter “Vaschillo”). Applicant respectfully traverses. The standards for anticipation are set forth above.

The Vaschillo reference also does not anticipate claim 1 and does not anticipate the other claims within the present patent application. In contrast to the present invention as claimed, the Vaschillo reference teaches spectrally analyzing a patient’s heart beat and respiratory signals in a passive fashion to generate spectral frequency information for the signals. The phase difference between the heart beat and the respiratory rates are compared and a phase difference is calculated. A single reference signal with a single phase indicator is generated and displayed along with the heart beat of the patient to indicate to the patient the relative phase of the patient’s breathing to the patient’s heart beat. Because the Vaschillo reference passively performs spectral analysis of the heart beat and the respiratory signals, the Vaschillo reference does not teach or suggest detecting transitions from a maximum or minimum heart rate of the patient.

As discussed above, claim 1 recites, among other things, “detecting a transition in the natural heart rate from a maximum heart rate . . .” and “detecting a transition in the natural heart rate from a minimum heart rate . . . .” Because the information that the Vaschillo reference uses to perform its phase difference calculations is frequency-based information generated through spectral analysis, the information is not the claimed transitions from maximum and minimum heart rates. Accordingly, the rejection of claim 1 based upon the Vaschillo reference should be withdrawn for at least these two reasons.

Additionally, the Vaschillo reference does not teach or suggest providing a first and second biofeedback signal to the human subject to indicate that the natural heart rate has reached the maximum and minimum heart rates, as distinctly claimed. The Patent Office has failed to

recognize that claim 1 distinctly claims two biofeedback signals. The single heart rate signal of the Vaschillo reference is not the two biofeedback signals (e.g., the first and second biofeedback signals) which distinctly indicate that the natural heart rate has reached the maximum and minimum heart rates, respectively, as claimed. Accordingly, the rejection of claim 1 based upon the Vaschillo reference should be withdrawn for at least these two additional reasons.

Applicant respectfully submits that the Vaschillo reference does not anticipate claim 1 because multiple limitations of claim 1 are not taught or suggested by the Vaschillo reference. Claims 3, 5, 7, 9, 11-15, 17-20, 22, and 24 depend, either directly or indirectly, from claim 1. Accordingly, the rejection of claims 3, 5, 7, 9, 11-15, 17-20, 22, and 24 should be withdrawn for at least the same reasons.

Additionally, regarding the rejection of claims 11-15 and 17-19, the Patent Office further asserts that the phase difference of the Vaschillo reference is considered to be an offset value as claimed. (See Office Action mailed January 26, 2007, p. 3). However, Applicant respectfully submits that the phase difference calculated within the Vaschillo reference is not an “offset” as claimed.

The Specification indicates, for example, that “[p]rogrammable offsets are provided on the basis of the present heart beat rate as a percentage of the peak hear beat rate, on the basis of the present heart beat rate vs. peak heart beat rate, on the basis of the absolute number of heart beats since peak heart beat rate, and on the basis of individual heart beats.” (See Specification, p. 8, ll. 10-14). Additionally, Figure 4 within the present application shows a maximum heart beat rate of 80 beats per minute and a minimum heart beat rate of 50 beats per minute. Figure 4 also shows detecting a transition from the maximum heart beat rate of 80 beats per minute at 79 beats per minute and shows detecting a transition from the minimum heart beat rate of 50 beats per minute at 51 beats per minute. The heart beat rates of 79 and 51 beats per minute represent an offset of 1 beat per minute from the maximum and minimum heart beat rates, respectively. Figure 4 also shows that the exhale and inhale biofeedback signals are generated at the peak values minus or plus the offset, respectively. These offsets are not phase differences.

Accordingly, the phase difference calculated within the Vaschillo reference is not the “offset” as claimed and the rejection of claim 11 should be withdrawn for at least this additional reason. Claims 12-15 and 17-19 depend from claim 11 and the rejection of claims 12-15 and 17-19 should be withdrawn for at least the same additional reasons.

Applicant respectfully submits that claims 1, 3, 5, 7, 9, 11-15, 17-20, 22, and 24 are in condition for allowance and notice of the same is requested at the earliest possible date.

Claims 1, 3, 5, 7, 9, 11-15, 17-20, 22, and 24 were provisionally rejected on the grounds of nonstatutory double patenting over claims 19-43 of copending Application No. 10/829,079. Applicant respectfully traverses. The Patent Office asserts that the subject matter of the instant application is fully disclosed in the referenced copending application and further asserts that the claims in the instant application are “merely broader in scope than [sic] the ‘079[.]” (See Office Action mailed January 26, 2007, pp. 3-4). However, Applicant respectfully submits that the claims of the present application are not merely broader in scope than the claims of the copending application. The claims of copending Application No. 10/829,079 are directed to determining whether an average heartbeat rate is stable, detecting positive and negative peaks in the heartbeat rate, and providing respective exhale and inhale signals in response to determining the heartbeat rate is stable. The claims within the present application are directed to detecting transitions from maximum and minimum natural heart rates and providing a first and second biofeedback signal, respectively. Accordingly, the claims within the present application are not merely broader than the scope of the copending application. The claims within the two applications claim distinct subject matter.

The Patent Office further asserts that “there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application.” (See Office Action mailed January 26, 2007, p. 4). However, for example, claim 1 of the present application claims detecting transitions from maximum and minimum natural heart rates and providing first and second biofeedback signals to indicate that the natural heart rate has reached the maximum and minimum, respectively. Additionally, claim 11 of the present application further claims “providing the first biofeedback signal at the maximum heart rate minus a first programmable offset; and providing the second biofeedback signal includes providing the second biofeedback signal at the minimum heart rate plus a second programmable offset.”

These claims are fully supported within the Specification of the present application. For example, Figure 4 within the present application shows a maximum heart beat rate of 80 beats per minute and a minimum heart beat rate of 50 beats per minute. Figure 4 also shows detecting a transition from the maximum heart beat rate of 80 beats per minute at 79 beats per minute and

shows detecting a transition from the minimum heart beat rate of 50 beats per minute at 51 beats per minute. The Specification indicates that the present invention “allows for the exact moment of the biofeedback to be adjusted so that timing may be optimized on a personal basis.” (See Specification, p. 6, ll. 28-30). For example, that “[p]rogrammable offsets are provided on the basis of the present heart beat rate as a percentage of the peak hear beat rate, on the basis of the present heart beat rate vs. peak heart beat rate, on the basis of the absolute number of heart beats since peak heart beat rate, and on the basis of individual heart beats.” (See Specification, p. 8, ll. 10-14).

As such, Applicant respectfully submits that the claims of the two applications are distinct and that the claims within the present application are not merely broader than the scope of the claims within the copending application. Applicant respectfully submits that the provisional nonstatutory double patenting rejection of claims 1, 3, 5, 7, 9, 11-15, 17-20, 22, and 24 over claims 19-43 of copending Application No. 10/829,079 should be withdrawn.

The present application is now in condition for allowance and such action is respectfully requested. The Examiner is encouraged to contact Applicant’s representative regarding any remaining issues in an effort to expedite allowance and issuance of the present application.

Respectfully submitted,

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